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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,179	03/27/2001	Ryo Nakashige	033808/027 8739	3835

7590

09/09/2003

Stanley P. Fisher
REED SMITH LLP
3110 Fairview Park Drive
Suite 1400
Fall Church, VA 22042

EXAMINER

MARSCHER, ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/819,179

Applicant(s)

NAKASHIGE ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

ABSTRACT

The abstract of the disclosure is objected to because it exceeds 150 words in length. A newly submitted abstract is required on its own separate sheet of paper. Correction is required. See MPEP § 608.01(b).

VAGUENESS AND INDEFINITENESS

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 5, the word "mediated" is set forth. The metes and bounds of what is meant regarding this practice are unclear. A common interpretation of a mediated practice is that some type of interaction occurs between the items being mediated. In the practice of instant claim 1, there is no indication that the genes being monitored in the various samples interact, however, mediation may indicate some type of interaction. Alternatively, is normalization meant of the data for Samples B and C versus data for Sample A? Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 1 also contain this unclarity due to their dependence.

In claim 1, lines 6-7, the phrase "commonly used in both experiments" is set forth. It is unclear whether this requires that the genes in Sample A must be utilized as a mixture during the preparation of Samples B and C or whether only the data from gene expression of Sample A is related in some way to the data from Samples B and C.

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Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 1 also contain this unclarity due to their dependence.

In claim 2, line 3, the word "taking" is set forth wherein levels are thus taken "on" the axes in line 4. It is confusing as to what is practiced to take levels "on" axes. One possible interpretation is that a x-, y-, z- system of axes are utilized for display of the expression results. Clarification via clearer claim wording is requested.

In claim 3, line 6, and claim 4, line 10, coordinate positions are obtained by a combination of expression levels. The claim lacks clear antecedent basis as to where such coordinate positions are generated as such positions are not defined in the claim in prior wording. Clarification via clearer claim wording is requested.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schena et al. (1996).

As disclosed in the title and abstract Schena et al. is directed to the monitoring of 1000 or more genes regarding expression. The last line of the abstract describes the analysis as being parallel gene analysis. On page 10614, second column, last sentence, the monitoring of the final fluorescence from the differential expression analysis was obtained as ratios of two independent hybridizations. In the RESULTS

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section on pages 10615-10617 the usage of control cells, Jurkat cells, as well as heat-treated 43°C cells, as well as Arabidopsis negative control cells were analyzed regarding their expressed mRNA content via microarray hybridization. The Jurkat cells served to provide samples which anticipate the instantly claimed A sample whereas B and C samples correspond to the heat-treated cells and Arabidopsis control cells, respectively. Figure 1 on page 10615 describes in the legend that the above samples were analyzed regarding expression levels as either being activated or repressed compared to the Jurkat control cells. Thus, the gene expression data anticipates the instant claim 1 plurality of gene expression analyses wherein multiple samples (at least B and C) are analyzed versus a commonly utilized sample A from Jurkat cells and the results are displayed in combination in the Figures as described in the legend albeit that Figure 1 is poorly reproduced. Figure 2 with Table 1 on page 10616 also anticipate instant claim 1 regarding displaying gene expression ratios for Jurkat treated cells, either with heat shock (Sample B as instantly claimed) or phorbol ester (Sample C) versus untreated cells labeled with Cy5 (Sample A). On page 10617 in the section entitled "Transcript Imaging in Human Tissue" the displaying of gene expression data from various tissue samples is described with normalization to Jurkat control cells (instant Sample A) and displayed in a 3-dimensional format on page 10618 in Figure 3 using x-, y-, and z- axes as in instant claim 2. See the above rejection under 35 USC 112, second paragraph as to unclear wording as to what is meant by the taking of expression levels on axes in instant claim 2.

No claim is allowed.

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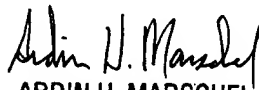
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 5, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER